

REMARKS

I. Preliminary Remarks

Claims 18, and 20-26 are now pending. Claim 18 has been amended to positively recite that the antigenic epitope is cross-reactive with an antibody that immunologically reacts with the Serpens genera and claims 20-26 have been newly added. No new issue has been raised requiring further search or consideration since the claims seek mere clarification of the present invention. Support for the amendment and the new claims can be found, for example, in the specification, at page 11, Table 1a and page 13, lines 11-12 and 15-16. No new matter has been added. Reconsideration and allowance of all of the claims in view of the following remarks is respectfully requested.

II. Rejection under § 112, First Paragraph

Claim 18 was rejected as not being enabled for pharmaceutical compositions of Serpens, immunologically active portions thereof, and antigenic epitopes cross-reactive with the Serpens genera. Applicants respectfully traverse this rejection.

Using a well known technique called epitope mapping, a person skilled in the art can identify and locate "immunogenically active portions" of bacterial species belonging to the genus Serpens and "an antigenic epitope that is cross-reactive with an antibody that immunologically reacts with the bacterial species."

In the process of epitope mapping, a bacterial species belonging to the Serpens genera may be cleaved into fragments using various enzymes. Sodium dodecyl sulfate-polyacrylamide gel electrophoresis (SDS-PAGE) may then be used to separate the generated fragments according to molecular weight and the fragments may then be transferred to a nitrocellulose membrane using immunoblotting techniques. In order to determine which fragment is immunologically active or contains the antibody binding site, an antibody probe may then be used.

Accordingly, the applicants respectfully submit that the specification with regard to Claim 18 is enabling for pharmaceutical compositions of Serpens, immunologically active portions thereof, and antigenic epitopes cross-reactive with the Serpens genera.

Notwithstanding, new claims 20-26 are added herein to address the rejection based upon Section 112, first paragraph. By claiming "immunogenic compositions" the newly added claims obviate the requirement of demonstrating a protective immunity has been elicited.

III. 102(b) References Cited

Claim 18 was rejected under 35 U.S.C. 102(b) as being anticipated by Hespell et al.

Applicants respectfully traverse this rejection. Hespell discloses live *Serpens flexibilis*. Hespell is intended to propagate live form of one particular species of the Serpens genera.

In that regard, Hespell does not disclosure, teach or suggest the attenuated form of species belonging to the Serpens genera. Nor does it disclose, teach, or suggest any other species belonging to the genus Serpens. Furthermore, as noted in the November 1, 2002 office action, Hespell does not set forth that the composition is used for the prevention and treatment of Papillomatous Digital Dermatitis in ruminants.

Therefore, Hespell et al. does not anticipate the pharmaceutical compositions or the immunogenic compositions as recited in the claimed invention. Hespell is specifically directed to the use of live *Serpens flexibilis* while the species claimed in the present invention are attenuated as would be recognized by a person of ordinary skill in the art. When the species are combined with a veterinarianily acceptable carrier, they are likely inactivated to prevent any virulent effect.

Notwithstanding, new claims are added which recite species that manifest negative reaction to Voges-Proskauer biochemical marker, i.e., do not produce acetoin from pyruvate which is distinguishable from a biochemical reaction displayed by *Serpens flexibilis* which reacts positive to Voges-Proskauer reaction.

Furthermore, new claims are added which recite species that do not reduce nitrite to nitrogen which is distinguishable from a biochemical reaction displayed by *Serpens flexibilis* which reduces nitrite to nitrogen.

With regard to claim 18, Hespell does not disclose, teach or suggest the presently claimed invention as discussed above. Accordingly, the above independent claim is in condition for allowance. With regard to new independent claims 20 and 24, Hespell teaches away from an attenuated bacterial species belonging to the genus Serpens. Accordingly, the newly added claims are in condition for allowance.

Additional references are provided to support the novelty of the present invention as follows:

The present invention satisfies a long-felt need which is expressed in Dairy Today (May 1998) p. 16, col.2, ¶ 2-4, "In recent years, Shearer has been advising commercial dairy producers

throughout Florida about footwart treatment. He has advocated topical antibiotic sprays alone, or combined with bandaging. ‘Producers are spending a lot of money on things that are ineffective for foowarts,’ he says. ‘I don’t see topical sprays, with or without bandaging, as solutions, [but] merely stopgap measures. We need a solution for footwarts.’”

Also many experts have expressed disbelief of the successful use of the present invention: “I don’t believe Hygieia [the applicants]’s vaccine will make footwarts better.” (Large Animal Practice, 19 (5), p. 39, ¶ 4).

“A number of different bacteria, including spirochetes, have been isolated. Researchers in Europe have found similar types of bacteria, however, none have reported isolating Serpens species.” (Large Animal Practice, 19(5), p. 39, col. 3, ¶ 2).

“Like several scientists around the world, Read is convinced that spirochetes play a role in the cause of PDD.” (Large Animal Practice, 19(5), p. 39, col. 3, ¶ 6).

“Many scientists and veterinarians in the field remain skeptical. While approximately 15 groups of researchers throughout the world are investigating PDD, Hygieia [the applicants] is the only known lab to have isolated the Serpens species bacteria in [sic] PDD legions.” (Dairy Today (May 1998), p. 15, col. 3, ¶ 5).

IV. Double Patenting

Applicants hereby submit a terminal disclaimer in compliance with 37 CFR 1.321.

V. Conclusion

With the above claimed invention fully enabling under Section 112 and distinguishable from the cited reference Hespell under Section 102, it is respectfully submitted that the independent claims and their respective dependant claims are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call Applicants’ undersigned representative at (213) 689-5176 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 07-1853. Should such additional fees be associated with an extension of time, Applicants respectfully request that this paper be considered a petition therefore.

Respectfully submitted,



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